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10/534,043	03/30/2006	Nobuo Sakaguchi	4456-0104PUS1	2803

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EXAMINER
HAMA, JOANNE

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Applicant filed a response to the Final Action of July 28, 2008 on December 29, 2008.

3. Amendments

Applicant has amended the claims such that they recite a requirement that the claimed transgenic mammals express a protein of SEQ ID NO. 2 or 4. This requires a new search and consideration as a sequence-based search was not required of the previously filed claims. Because the amendment raises a new issue, the claims filed December 29, 2008 will not be entered and Applicant's response, as they apply to the claims filed April 10, 2008 will be considered.

11. Request for Reconsideration/ Other

Claim Objection

Applicant's arguments filed December 29, 2008 have been fully considered but they are not persuasive. Applicant indicates that claim 15 was objected to and has amended claim 15. In response, this is not persuasive as the claims of December 29, 2008 have not been entered.

35 USC § 112, 1st parag., Enablement

Applicant's arguments filed December 29, 2008 have been fully considered but they are not persuasive.

Applicant indicates that claims 1, 5, 12 are amended to specify the transgenic non-human mammals encompassed by the claims. Applicant indicates a skilled artisan

using the guidance in the present application regarding the expression of GANP in mice coupled with the knowledge generally available to one of skill in the art regarding the generation of transgenic mammals is sufficient to allow a skilled artisan to practice the claimed invention (Applicant's response, page 6). In response, this is not persuasive, as making mouse does not enable a variety of transgenic mammals. See Office Action of October 11, 2007, pages 9-10.

Applicant indicates that the present application provides guidance to enable an artisan to recognize that the described transgenic animals produce high affinity antibodies. As is understood by the skilled artisan, increased somatic hypermutations in transgenic animals are associated with affinity maturation of hapten specific B cells and enhanced antibody affinity. Applicant indicates that the claims do not describe specific mutations, and as such the Examiner's scope is outside of the instant claims (Applicant's response, page 6). In response, this is not persuasive. The Examiner was not indicating that the claims were required to recite specific mutations. Rather, the Examiner was reciting what was taught in the specification with regard to the characteristics of the antibody and genome of the mice described in the specification, and that the specification does not provide guidance that the claimed non-human mammals necessarily produced high affinity antibody (Office Action, October 11, 2007, pages 11-14).

Applicant indicates that the antibodies made by the transgenic GANP mice are high-affinity antibodies. Applicant refers to Figure 29, which demonstrates that high-affinity antibodies are made by the GANP transgenic mice (Applicant's response, pages

6-7). In response, this is not persuasive. As indicated in the Office Action of October 11, 2007, page 12, Figure 29 is not conclusive that the GANP transgenic mice necessarily produce high-affinity antibodies. Figure 29 illustrates that not all hybridomas tested were high-affinity antibodies. In addition to indicating that six hybridomas were tested and Figure 29 only showing 4 hybridomas, Figure 29 also shows that one hybridoma appears to have the same affinity as the control hybridoma. Further, Figure 29 shows only one control hybridoma; it is unclear whether that one control hybridoma is representative of a number of control hybridomas, as the art in general indicates that control hybridomas show a range of ability to bind to antigen. An artisan cannot reasonably predict from the results that antibodies from GANP mice are necessarily high-affinity.

With regard to the claims encompassing the use of ES cells (e.g. claim 3), Applicant provides no response and the rejection as it applies to this issue remains. See Office Action, July 28, 2008, page 6.

35 USC § 112, 2nd parag.

Applicant's arguments filed December 29, 2008 have been fully considered but they are not persuasive. Applicant indicates that claims 17-19 have been amended. In response, this is not persuasive as the claims have not been entered.

35 USC § 103

Applicant's arguments filed December 29, 2008 have been fully considered but they are not persuasive. Applicant indicates that in contrast to the instant claims, Kuwahara et al. fails to teach or suggest the regulation of the GANP gene at a

molecular level. Further, Kuwahara et al. do not teach or provide guidance of how the GANP gene would function in an in vivo system, and in particular a transgenic mammal. Specifically, Kuwahara fails to teach or suggest a transgenic non-human mammal comprising a transferred recombinant mouse GANP gene or human GANP gene. Janenisch and Mass, which teach the use of heterologous promoters for tissue specific expression, and Henderson, which describes Ig expression in B-cells fail to remedy the deficiencies of Kuwahara (Applicant's response, page 9). In response, this is not persuasive. As discussed in the Office Action, July 28, 2008, Kuwahara et al. provide guidance that GANP was of interest and that it appeared to have a role in the cell cycle. However, not much was known about the biological role of the protein. Janeisch was provided to teach that making transgenic overexpression animals was known in the art and that overexpression of a gene of interest would reveal not only the pathological consequences of unregulated or ectopic expression of the transgene, it will also help in the analysis of its normal function in development and differentiation. As such, the art provides guidance to make a GANP overexpression non-human mammal.

Applicant indicates that the transgenic animals described in the instant claims produce high-affinity antibodies. An artisan could not have predicted from the documents provided by the Examiner that expressing GNAP in non-human mammals would have resulted in this beneficial phenotype (Applicant's response, pages 9-10). In response, this is not persuasive. As discussed above, guidance was provided to combine the references to arrive at the claimed non-human mammals. As written, the claims' only requirement was to arrive at a transgenic non-human mammal with a

particular genomic structure; i.e. comprise a GANP expression construct. The art provides guidance to arrive at these non-human mammals. Further, it is noted that the reasons to combine references do not necessarily have to be the same as that of the Applicant. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

12. Request for Reconsideration/Other, IDS

Applicant filed an IDS and the statement according to 37 CFR § 1.97(e) and paid the 37 CFR §1.17(p) fee. The IDS has been considered.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Joanne Hama/
Primary Examiner
Art Unit 1632